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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,897	11/28/2000	Gustave Bergnes	CYTOP009C5	1088

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EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT PAPER NUMBER

1624

DATE MAILED: 05/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/724,897	Applicant(s) BERGNES ET AL.	
	Examiner Tamthom N. Truong	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31,50,60,64 and 68-77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31,50,60,64 and 68-77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11-12-03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10-09-03 has been entered.

Claims 31, 50, 60, 64, and 68-77 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. **Lack of Written Description:** Claims 31 and 50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Both claims recite the limitation of “*wherein said compound has a chiral purity of >95%*”. The instant disclosure does not describe a process for obtaining the claimed compound with a chiral purity of >95%. Example 9 in the disclosure only describes the chiral resolution for quinazolinone compounds having $-\text{CH}(\text{C}_2\text{H}_5)-$

Art Unit: 1624

$\text{N}(\text{CH}_2\text{CH}_2\text{NH}_2)\text{-C(=O)-}(\text{Ph-Br})$ at the second position. It appears that the instant compounds are intermediates which are obtained as a racemic mixture rather than a pure enantiomer or diastereomer of R- or S- configuration. Therefore, the claim of "*a chiral purity of >95%*" does not have support, and thus, lacks a written description.

3. **Enablement:** Claims 31 and 50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In view of the lack of written description, clearly claims 31 and 50 do not have sufficient enablement for guiding one skilled in the art in obtaining the claimed compound with "*a chiral purity of >95%*".

4. **Lack of Written Description:** Claims 68-71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 68 and 70 recite the limitation of "halobenzyl" which does not have a description in the instant disclosure. The sole species of "chlorobenzyl" does not adequately support the scope of "halobenzyl".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1624

5. **Indefiniteness:** Claims 31, 50, 60, 64, and 68-77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Said claims recite the limitations of “*substituted lower alkyl*”, “*substituted benzyl*”, “*substituted aryl*”, “*substituted heteroaryl*”, “*substituted alkylaryl*”, “*substituted alkylheteroaryl*”, etc. which render the claims with indefinite metes and bounds. In the absence of the specific moieties intended to effectuate modification by “substitution” or attachment to the chemical core claimed, the term “substituted” renders the claims in which it appears indefinite in all occurrences wherein applicant fails to articulate by chemical name, structural formula or sufficiently distinct functional language, the particular moieties applicant regards as those which will facilitate substitution, requisite to identifying the composition of matter claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Art Unit: 1624

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 60 and 64 are rejected under 35 U.S.C. 102(e) as being inherently anticipated by **Schall et. al.** (US 6,559,160 B1—claiming priority to a Provisional Application of 60/151,212 filed on August 27, 1999). On column 28, Example 3.4 discloses compound j which reads on the compound recited in the following claims:

a. Claim 60: a pharmaceutical composition wherein the quinazolinone compound has the following substituents:

- i. R_1 is a substituted aryl group;
- ii. One of R_2 and $R_{2'}$ is a hydrogen, and the other is an alkyl group;
- iii. R_4 is R_{16} -alkylene-; wherein R_{16} is a dialkylamino group;
- iv. R_6 is an alkoxy group while R_5 , R_7 and R_8 each represents a hydrogen;

b. Claim 64: a pharmaceutical composition wherein the quinazolinone compound has the following substituents:

- v. R_1 is a substituted phenyl group;
- vi. $R_{2'}$ is a hydrogen, and R_2 an alkyl group;
- vii. R_4 is R_{16} -alkylene-; wherein R_{16} is a di(lower alkyl)amino group;

Art Unit: 1624

viii. R_6 is an alkoxy group while R_5 , R_7 and R_8 each represents a hydrogen;

The pharmaceutical composition is taught on column 12 of US'160 B1. Although the reference does not mention the R-configuration, it is inherently in the chemical structure of the compound that the chirality exists at the carbon of $-\text{CH}(\text{Me})-\text{NH}-$, and thus the possibility of R- and S- configuration also exists.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-F (~10 am ~ 6:30 pm).

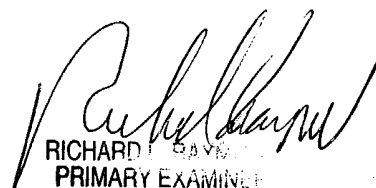
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached at 571-272-0674. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting SPE of 1624, at 571-272-0661.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



T. Truong

May 9, 2004



RICHARD D. SAVILLE
PRIMARY EXAMINER
ART UNIT 1624